



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/542,958

01/30/2007

William R. Jacobs JR.

96700/1031

2060

1912

7590

11/20/2008

AMSTER, ROTHSTEIN & EBENSTEIN LLP
90 PARK AVENUE
NEW YORK, NY 10016

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,958	Applicant(s) JACOBS ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,8,10,12,13,16-19,22-25,28,30,32,38,39,41 and 87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,10,12,13,16-19,22-25,28,30,32,38,39,41 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

1. Applicants' Response to Office Action, received 3 July 2008, is acknowledged. Claims 1 and 41 have been amended. New claim 87 has been added.
2. Claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39, 41, and 87 are pending and under consideration.

Rejections/Objections Withdrawn

3. The objection to Figure 1 is withdrawn in light of the submitted replacement sheet.
4. The objection to Figure 2 is withdrawn in light of the submitted replacement sheet.
5. The objection to Figure 3 is withdrawn in light of the submitted replacement sheet.
6. The objection to Figure 4 is withdrawn in light of the submitted replacement sheet.
7. The objection to Figure 5 is withdrawn in light of the submitted replacement sheet.
8. The objection to Figure 6B is withdrawn in light of the submitted replacement sheet.
9. The objection to Figure 18B is withdrawn in light of the submitted replacement sheet.
10. The objection to Figure 25 is withdrawn in light of the submitted replacement sheet.
11. The rejection of claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39, and 41 under 35 U.S.C. 112, second paragraph, as being indefinite for metes and bounds of invention, is withdrawn in light of the amendment of the claims.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39, 41, and 87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inoculation of mammals against *M. tuberculosis* by administration of *M. tuberculosis* H37Rv mutants, does not reasonably provide enablement for inoculation of mammals against all species of mycobacteria in the *M. tuberculosis* complex. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – inoculation of mammals against a *M. tuberculosis* complex by administration of an attenuated deletion mutant mycobacterium in the *M. tuberculosis* complex.

The state of the prior art as taught by applicants' specification indicates that "numerous vaccines against tuberculosis have failed" (Grange et al, 1983) (pages 11-12) and that Chambers et al, 2000, teach that both BCG and BCG mutants seemed to protect better against *M. bovis* challenge than *M. tuberculosis* (page 13).

Art Unit: 1645

Thus, there appears to be a lack of predictability in the art that one deletion mutant species of the *M. tuberculosis* complex will effectively inoculate a mammal against another species of the *M. tuberculosis* complex.

The amount of direction or guidance present is insufficient for the broad scope of the instant claims because the specification utilizes only deletion mutants of *M. tuberculosis* H37Rv and *M. bovis* BCG as vaccines against *M. tuberculosis* Erdman.

Therefore, the quantity of experimentation necessary to determine which, if any, deletions in one or all of the species present in the *M. tuberculosis* complex would successfully inoculate a mammal against any/all other species of *M. tuberculosis* complex constitutes merely an invitation to experiment without a reasonable expectation of success.

14. Claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39, 41, and 87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, claim 1 is now drawn to a method for inoculating a mammal against "a" *M. tuberculosis* complex. It is unclear what is meant by the singular "a". There is but one *M. tuberculosis* complex, although the complex is made up of several *Mycobacterium* species. Clarification is required.

Claims 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39, 41, and 87 are dependent claims, but do not clarify the issue.

Conclusion

15. Claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39, 41, and 87 are finally rejected.

Art Unit: 1645

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR


Art Unit: 1645

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 20, 2008

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/542,958	JACOBS ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	